

REMARKS

The present amendment is designed to remove any necessity of having a Terminal Disclaimer in the present case.

According to Applicant's records, the original file in this case (parent application 08/872,023 had a restriction requirement and 09/200,743 (the present application) was filed as a division thereof. A Preliminary Amendment on 11/15/1998 limited the claims to subject matter that was not elected in the parent. Thus, no Terminal Disclaimer was needed at that time. In fact, the Action of 12/7/1999 did not mention any obviousness double patenting or need for any Terminal Disclaimer.

On February 23, 1999, US 5,874,447 issued from Applicant's parent application (Ser. No. 08/872,023). The present application was filed November 30, 1998 as a divisional application after a Restriction in the parent case and at that time was directed to the non-elected subject matter of the parent case. In May 2000, US 6,063,927 (owned by SmithKline Beecham) issued having US 5,874,447 listed as art in that case. The '927 patent was directed to crystalline paroxetine methanesulfonate having specified IR peaks. In light thereof, in November 2000, Applicant amended its application to include claims directed to crystalline paroxetine methanesulfonate (claim 32); crystalline paroxetine methanesulfonate having specified IR peaks (claim 31), crystalline paroxetine methanesulfonate crystallized from ethyl acetate (claim 30) and parallel claims to compositions thereof (claims 33-35), methods of treatment therewith (claims 36-38) and a process of making paroxetine hydrochloride from paroxetine methanesulfonate (claim 39). With that amendment, Applicant requested a Declaration of Interference. Applicant had discussed the claims in an Interview on November 1, 2001, in which the subject matter of claim 39 was questioned as potentially not being patentably distinct from the subject matter of Applicant's parent application (then issued US 5,874,447). At that time, there was no assertion that the other claims (30-38) were also of concern in this regard. In order to deal with the issue of claim 39, Applicant advised the Examiner that a Terminal Disclaimer would be filed to remove the issue raised concerning claim 39. The Terminal Disclaimer was filed on January 31, 2001.

Two counts were proposed for the Interference, one dealing with Applicants claims 30-32 and the '927 Patent claims 1 and 3; and a second count dealing with Applicant's claim 39 and the '927 patent claims 2 and 4.

In response, on February 21, 2001, the Examiner suspended prosecution for 6 months, and on April 26, 2001, the Examiner issued a Restriction Requirement between claims 30-38 on the one hand and claim 39 on the other. On May 29, 2001, Applicant then elected claims 30-38 and cancelled claim 39. On August 2, 2001, the Examiner indicated that claims 30-38 were allowable but that due to an Interference, prosecution was suspended.

The Interference was concluded on May 25, 2004 with a Decision in Applicant's favor. The undersigned attorney became an attorney of record in this case in April 2006 and inquired as to the application status with a written Status Request on April 25, 2006. Upon being advised that the application was finally located and being transferred back to the Examiner, Applicant filed a request to Withdraw the Terminal Disclaimer (on the basis that the reason for its submission was claim 39, which was no longer in the case) on November 16, 2006. Applicant was advised (at the time of filing that request) that a Petition to Withdraw the Terminal Disclaimer would be needed as well, and Applicant filed the same on November 16, 2006 as well. That Petition was dismissed on July 11, 2007 on the basis that the Examiner felt that claim 32 merely differed from a claim of the '447 Patent in that it specified "crystalline", but nothing more ('447 has a claim to "paroxetine organic sulfonate salts" (claim 1). Applicant here acknowledges that claim 21 of the '447 patent is narrower and claims "paroxetine methanesulfonate" so that the closest claim to the present application claims 30-32 is the '447 Patent claim 21 and thus, applicant believes the Examiner intended to specify '447 patent claim 21 rather than claim 1 as her basis for maintaining the need for the terminal disclaimer.

It should be noted that during the prosecution of the '927 Patent (the claims there were originally directed to paroxetine methanesulfonate and were rejected over Applicant's '447 Patent. In response, applicant amended the claims to include the recitation of "crystalline" and the IR peaks appearing in those claims, after which, the Examiner there (not the present case Examiner, allowed '927 Patent claims). Thus, there is ample justification for a conclusion that the crystalline

paroxetine methanesulfonate claims (at least as far as being inclusive of specific IR peaks) is a patentably distinct invention over the genus of "paroxetine methanesulfonate".

During a discussion of these issues with the present Examiner on September 11, 2007, the Examiner indicated that she would consider claim 31 as a patentably distinct invention over the '447 Patent, but not claims 30 or 32, and not claims 33-38. Claims 30 and 32, according to the Examiner were considered too broad, without the IR peaks, merely eliminating "amorphous" from the general '447 Patent claim 21. Concerning claims 33-38, the Examiner asserted that she would require additional data to show that the compaction into tablets (re claim 33-35) did not result in a change of polymorphic form, and that dissolution or delivery was not altered in some way due to the specific polymorph being present for a conclusion that these claims (even if limited to the claims having the IR peaks) were patentably distinct from the '447 Patent.

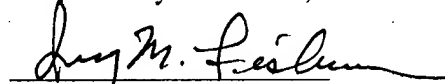
In order to advance this case and have the Terminal Disclaimer removed in this case, Applicant has therefore canceled claims 30 and 32-38 subject to Applicant's right to refile such claims.

For the Examiner's information, Applicant intends to file a daughter Application with claims directed to the subject matter of currently canceled claims 30 and 32-38 with the appropriate Terminal Disclaimer as may be appropriate. Concurrently herewith, Applicant (as directed by the Examiner and Mr. Thurman Page (Petitions Branch) is filing a Request for Reconsideration of the prior Petition to Withdraw the Terminal Disclaimer.

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Respectfully submitted,



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